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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/516,983

12/03/2004

Luppo Edens

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EXAMINER

LILLING, HERBERT J

ART UNIT

PAPER NUMBER

1657

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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31 DAYS

02/05/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/516,983

Applicant(s)

EDENS ET AL.

Examiner

HERBERT J. LILLING

Art Unit

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on December 03, 2004(Preliminary Amd).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 03 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

1. Receipt is acknowledged of a preliminary amendment and a prior art information disclosure statement filed December 03, 2004 and a prior art information disclosure statement filed July 07, 2005 for this application which is a 371 of PCT/EP {03/05876 filed June 03, 2003 which claims benefit to EPO 02100667.1 filed June 04, 2002.
2. Claims 1-24 is now present in the instant application.
3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-5 and 16-21, drawn to a **first product which for** a protein hydrolysate which is rich in dipeptides whereby the tripeptides are rich in proline at one end thereof, classified in Class 435, subclass 68.1.

Group II, claims 6-8 and 22 drawn to a **method of producing a protein** hydrolysate comprising contacting a protein substrate with a) endoprotease and b) tripeptidase (TPAP), classified in Class 435, subclass 68.1.

Claims 9 and 23 are drawn to non-statutory matter as not being within the requirements of 35 USC 101 as having a specific utility.

Group III, claims 10-12 and 24 drawn to a **second product** which is for a enzyme composition comprising (a) an endoprotease and (b) a tripeptidase (TPAP), classified in Class 435, subclass 212.

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Group IV, claim 13, drawn to third product which is for a food or feed product comprising the hydrolysate of a protein hydrolysate which is rich in tripeptides whereby the tripeptides are rich in proline at one end thereof, class in Class 514, subclass 18.

Group V, claims 14 or 15, drawn to a methods of incubating a protein substrate found in proline rich food stuffs with an enzyme composition comprising (a) an endoprotease and (b) a tripeptidase (TPAP) which method produces food or feed from the incubated substrate, classified in Class 424, subclass 94.2.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same as clearly indicated in the parent PCT as the various inventions lack the single general inventive concept.

In addition, Invention I does not require the specifics of Invention II or Invention III. Inventions IV and V do not require the specifics of Invention I.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, as well as due to their recognized divergent subject matter, and computerized searches would require different strategies for each of the separate and distinct inventions that would also be extremely burdensome on this Examiner to search and examine the additional inventions, thus the restriction for examination purposes as indicated is proper according to the M.P.E.P.

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4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

A. Whereby the protein hydrolysate having a molecular weight in the range of 200 to 2000 Da wherein proline is present as tripeptides in which at least the molar % of proline is at least:

- i> 20%;
- ii> 25%
- iii> 30%;
- iv> 40%;
- v> other-please specify.

Applicant is requested to provide the structure of the protein hydrolysate since each molecular weight is drawn to a different structure. The differences in the tripeptides is evidence of different structures and different structures requires specific structural sequencing. Absent a structure for the claimed products for Invention I, it is advised that this set of claims drawn to these specific features will be considered as being not supported by the specification.

B. Whereby the protein hydrolysate which is rich in tripeptides whereby the tripeptides are rich in proline at one end thereof has wherein the tripeptides having a carboxy terminal proline is at least :

- a> 30% of the tripeptides;
- b> 35%
- c> other please specify the %.

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C. Whereby the protein hydrolysate has a molar % of peptides present in the hydrolysate contains 2 to 7 amino acid residues which molar % is at least

- a> 70%
- b> 75%
- c> other-please specify.

D. Whereby the method employs or an enzyme composition contains an endoprotease which is selected from:

- a> endoprotease;
- b> proline specific endoprotease (PSE);
- c> aspartic protease;
- d> metalloendoprotease;
- e> other-please specify;
- f> combination of above a>-e>-please specify the combination.

E. Whereby in the method, the protein substrate is first contacted with:

- a> serine protease;
- b> aspartic protease;
- c> metalloendoprotease.

F. Whereby in the method, the protein substrate is contacted after the first step (above E) with:

- a> TPAP alone;
- b> TPAP plus proline specific endoprotease ;
- c> other-please specify.

Applicant is required, in reply to this action, to elect a **single species** from each of the above species noted in A-F to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

5. Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention, I-V, and elections of species to be examined even though the requirement be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.**

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the

record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103 (a) of the other invention.

This Examiner advises Applicant to contact this Examiner for any clarification or assistance pertaining to the restriction and/or election requirements. It is advised that Applicant be very careful in identifying the claims readable on the elected species, including any claims subsequently added that encompasses the claims within the elected invention containing all of the elected species.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. In accordance with this Tech Center 1600 Policy for rejoinder of claims, the following guidelines are submitted in view of Ochiai/Brouwer Decisions:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or**

otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

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8. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

On page 16, line 29, it is suggested that the heading should be changed to:

BRIEF DESCRIPTION OF THE FIGURES to comply with the USPTO office policy.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Lilling whose telephone number is 571-272-0918 and Fax Number is **571-273-8300**, or SPE Jon Weber whose telephone number is 571-272-0925. Examiner can be reached Monday-Friday from about 7:30 A.M. to about 7:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit **1657**
January 29, 2007



Dr. Herbert J. Lilling
Primary Examiner
Group 1600 Art Unit 1657